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STUDENT NOTES

TECHNICALLY SPEAKING, DOES IT MATTER? AN EMPIRICAL STUDY
LINKING THE FEDERAL CIRCUIT JUDGES' TECHNICAL BACKGROUNDS
TO HOW THEY ANALYZE THE SECTION 112 ENABLEMENT AND
WRITTEN DESCRIPTION REQUIREMENTS

DUNSTAN H. BARNES*

INTRODUCTION

At the heart of the patent system is a relatively simple *quid pro quo* transaction; in exchange for disclosing his or her invention to the public, an inventor is given the right to exclude others from using it.¹ This property right, known as a patent, can be tremendously valuable. For example, in July 2011, a consortium of companies including Apple, Microsoft, and Sony paid \$4.5 billion for Nortel's portfolio of 6,000 patents.² In response, Google paid \$12.5 billion in August 2011 to acquire Motorola Mobility³ and its extensive patent portfolio of more than 17,000 patents.⁴ With so much money at stake, "patent lawyers, inventors, and technology corporations . . . must be able to base their research and development, and their patent decisions, on well-established rules."⁵

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1. See *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150–51 (1989). A patent gives its owner a property right that is commonly—but mistakenly—believed to give the owner a "right to use" the invention. Indeed, inventors often develop and patent inventions that are partially covered by another patent or patents. Rather, in exchange for publicly disclosing their inventions, inventors are given the right, for a limited time, to *exclude* others from making, using, selling, offering to sell, or importing their inventions. See 35 U.S.C. § 271(a) (2012).

2. Chris V. Nicholson, *Apple and Microsoft Beat Google for Nortel Patents*, N.Y. TIMES (July 1, 2011), <http://dealbook.nytimes.com/2011/07/01/apple-and-microsoft-beat-google-for-nortel-patents/>.

3. Evelyn M. Rusli, *How Google-Motorola Deal Came Together*, N.Y. TIMES (Sept. 13, 2011), <http://dealbook.nytimes.com/2011/09/13/how-the-google-motorola-deal-went-down/>.

4. At the time of the sale, Motorola's patent portfolio consisted of more than 17,000 patents. Evelyn M. Rusli & Claire Cain Miller, *Google to Buy Motorola Mobility for \$12.5 Billion*, N.Y. TIMES (Aug. 15, 2011), <http://dealbook.nytimes.com/2011/08/15/google-to-buy-motorola-mobility/>.

5. Chief Judge Glenn L. Archer, Jr., *Conflicts and the Federal Circuit*, 29 J. MARSHALL L. REV. 835, 835 (1996).

One such rule is that an inventor must sufficiently disclose the technological secrets of his or her invention in the patent specification.⁶ If an inventor fails to keep his or her end of the patent bargain by inadequately disclosing the invention, the inventor may forfeit his or her exclusive rights for that invention. If an inventor fails to comply with the requirements of 35 U.S.C. § 112 (Section 112 of the Patent Act), the inventor's patent application may be denied prior to issuance by the United States Patent and Trademark Office (PTO) or the inventor's issued patent may be invalidated later by a court. Because a patent is presumed valid once issued by the PTO, an inventor is probably more likely to have his or her patent application rejected by the PTO than to have his or her patent invalidated by a court.⁷ This presumption of validity means that a party (such as an accused infringer) seeking to invalidate an issued patent must show that the patent is invalid by "clear and convincing" evidence.⁸ However, because an accused infringer tends to have a much more powerful incentive than the PTO to closely scrutinize whether a patent satisfies the Section 112 requirements, accused infringers may realistically be able to meet this heightened burden.

One might hypothesize that how judges interpret a patent's presumption of validity would depend on their "technical expertise"—their educational and professional training in scientific or technical areas. The present study focuses on whether the level of technical expertise of judges on the Court of Appeals for the Federal Circuit affects their analysis of the disclosure requirements under Section 112 of the Patent Act. The Federal Circuit has been the exclusive venue for appeals in the majority of patent disputes since it was founded in 1982.⁹ Since its foundation, the Federal Circuit "has become the *de facto* supreme court of patents."¹⁰

There are numerous ways to collect data about the Federal Circuit judges' technical backgrounds and patent law jurisprudence.¹¹ For

6. These requirements are set forth in 35 U.S.C. § 112, ¶ 1 (2012).

7. *Id.* at § 282.

8. *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 715-16 (Fed. Cir. 1991). "The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." 35 U.S.C. § 282 (2012).

9. Rochelle Cooper Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1, 7 (1989).

10. Mark D. Janis, *Patent Law in the Age of the Invisible Supreme Court*, 2001 U. ILL. L. REV. 387, 387 (emphasis added).

11. See R. Polk Wagner & Lee Petheridge, *Is the Federal Circuit Succeeding? An Empirical Assessment of Judicial Performance*, 152 U. PENN. L. REV. 1105, 1125 (2004).

example, one could conduct surveys of judges, patent practitioners, or scholars about the methodologies that they use or have observed.¹² This approach would provide information, but could be badly hampered by validity problems, “including the possibility of systematic bias, the difficulties in developing reliable survey instruments, and (for judicial surveys) the general unreliability of responses received from those persons under study.”¹³

Another possibility—an empirical approach that avoids the dangers involved in using surveys¹⁴—is to examine judicial decisions to see how Federal Circuit judges are actually applying the law. The present empirical study aims to examine what the Federal Circuit judges are actually *doing* rather than what they are merely *saying*.¹⁵ This empirical approach can provide extremely useful results. Although “[e]mpirical work is . . . a devilish enterprise in the legal sphere,”¹⁶ and “[empirical] data must be interpreted with care,”¹⁷ an empirical study can provide insights that may not be readily visible by other approaches, such as those that focus solely on the language of the Federal Circuit’s opinions.

The present empirical study will examine the Federal Circuit’s decisions over the past fifteen years of its almost thirty-year history—from January 1, 1997 until December 31, 2011—and will focus solely on the Section 112 disclosure requirements. A major advantage of focusing on a specific area of patent law—such as the Section 112 disclosure requirements—is that there is a lesser risk of missing insights that could be hidden by the sheer breadth of a fully-inclusive study. That is, a broader approach examining the Federal Circuit’s overall reversal rate across *all* patent cases would likely generate results that mask the fact that the Federal Circuit is very deferential to lower courts in some areas of patent law, but not deferential at all in other areas. For example, due to differing standards of appellate review, the Federal Circuit is supposed to be highly deferential to lower courts on

12. See *id.* at 1125-26.

13. *Id.* at 1126 (footnote omitted).

14. *Id.*

15. Although an empirical study could be used to evaluate what the judges are saying, too.

16. Rochelle Cooper Dreyfuss, *The Federal Circuit as an Institution: What Ought We to Expect*, 43 LOY. L.A. L. REV. 827, 831 (2010).

17. *Id.*

issues of fact, such as infringement,¹⁸ but is supposed to pay no deference to lower courts on issues of law, such as claim construction.¹⁹

This paper is divided into four parts. Part I provides an introductory background to U.S. patent law, the creation of the Federal Circuit, the Section 112 enablement and written description requirements, and the purpose of the present study. Part II describes the design of the empirical study, including the techniques used to find and select cases, the criteria analyzed, and some limitations of the study design. Part III sets forth the results of the study, which includes separate analyses of the results based on different factors, such as the Section 112 requirement at issue, the technical backgrounds of the Federal Circuit judges hearing the case, and the year of the decision. Finally, Part IV contains considerations about some of the implications of the results, how these implications could be utilized, and a mention of what direction the Federal Circuit may move in vis-à-vis enablement and written description issues.

I. BACKGROUND

A. *Patent Law in the United States*

The Framers of the U.S. Constitution recognized a need to provide an incentive for inventors to disclose their inventions to the public. Article I, § 8, cl. 8 of the Constitution grants Congress “Power . . . [t]o promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries.”²⁰ The Patent Clause contains both a grant of power and limitations upon the exercise of that power.²¹ That is, despite granting Congress the power to “implement the stated purpose of the Framers” by enacting suitable patent acts to secure patents for inventors,²² the Patent Clause prevents Congress from (1) creating patent monopolies of unlimited duration²³ or (2) “authoriz[ing] the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available.”²⁴

18. See *Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1323 (Fed. Cir. 2000).

19. See *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454–55 (Fed. Cir. 1998).

20. U.S. CONST. art. I, § 8, cl. 8.

21. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989).

22. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 6 (1966).

23. *Bonito Boats*, 489 U.S. at 146.

24. *Graham*, 383 U.S. at 6.

B. Patent Structure and Patent Litigation

Striking the proper balance between patent protection coverage and the extent of an inventor's contribution can be extremely difficult.²⁵ "If courts strictly limit the scope of patent protection to the specific examples disclosed in the patent, competitors could readily circumvent the patent through minor changes in design. But if the protection is advanced too liberally, then the patentee could obtain a windfall that strangles future technical advance."²⁶

Each patent application contains a patent specification, which describes the invention sought to be protected and concludes with one or more claims "particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."²⁷ The claims are the most significant part of the patent application, because they define the scope of the protection of the patent.²⁸ The term "specification" is most commonly used to refer to the portion of the patent that includes a summary of the invention, a detailed description of the invention, and drawings of the invention. Even though the claims "define the invention,"²⁹ a patent will be invalid if its specification fails to fulfill certain requirements,³⁰ such as the Section 112 enablement and written description requirements, which are described below.

C. Enablement and Written Description Requirements

Section 112, Paragraph 1 of the patent statute provides:

The specification shall contain a *written description* of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to *enable any person skilled in the art to which it pertains*, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.³¹

25. MARTIN J. ADELMAN ET AL., CASES AND MATERIALS ON PATENT LAW 414 (3d ed. 2009).

26. *Id.*

27. 35 U.S.C. § 111(a)(2)(A) (2012); 35 U.S.C. § 112, ¶ 2 (2012).

28. ADELMAN, *supra* note 25, at 459.

29. *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004); *Aro Mfg., Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 339 (1961).

30. *See, e.g., Gould v. Hellwarth*, 472 F.2d 1383, 1388 (C.C.P.A. 1973) (in which a patent directed to a laser was held to be invalid for failing to provide an enabling disclosure of how to make a laser).

31. 35 U.S.C. § 112, ¶ 1 (2012) (emphasis added). This paragraph also contains a "best mode" requirement that is no longer grounds for invalidating issued patents under the Leahy-

The main purposes of this requirement are to force inventors to sufficiently describe the invention so that a person having ordinary skill in the art could make and use the invention without undue experimentation³² and to demonstrate that the inventors were fully in possession of the claimed invention at the time that the patent application was filed.³³ This latter purpose limits inventors from asserting patent rights beyond what the inventors actually contributed to the relevant field.³⁴ The written description requirement limits inventors' patent rights to the invention disclosed at the time of filing the patent application. If we use a "fence" to define the scope of an invention, inventors have exclusive rights to embodiments of the invention that fall within the fence. Inventors do not have exclusive rights to embodiments that fall outside of the fence, and such embodiments would not infringe the patent.

Courts—such as the Federal Circuit—have hotly debated whether Section 112, Paragraph 1 contains separate enablement and written description requirements.³⁵ Although these debates began prior to the Federal Circuit's creation,³⁶ Federal Circuit judges have continued to argue whether the written description requirement includes a "free-standing disclosure requirement, above and beyond the enablement requirement of Section 112."³⁷ A combined enablement and written description requirement would mean that "the description of the invention is judged only by enablement—namely, whether it describes in such full, clear, concise, and exact terms as to enable any person skilled

Smith America Invents Act that was signed into law on Sept. 16, 2011, even though an inventor must still set forth the best mode when applying for a patent.

32. *In re Cortright*, 165 F.3d 1353, 1356 (Fed. Cir. 1999) ("A lack of enablement rejection under section 112, ¶ 1 is appropriate where the written description fails to teach those in the art to make and use the invention as broadly as it is claimed without undue experimentation.").

33. *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345 (Fed. Cir. 2000) ("The purpose of this provision is to ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification.").

34. *Id.*

35. *See, e.g., Ariad Pharms., Inc. v. Eli Lilly & Co.*, 560 F.3d 1366, 1371, 1380 (Fed. Cir. 2009) (in which the majority and concurring opinions disagree about whether § 112 requires a separate written description).

36. Margaret Sampson, *The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. § 112 in the Area of Biotechnology*, 15 BERKELEY TECH. L.J. 1233, 1252 (2000).

37. R. Polk Wagner, *The Two Federal Circuits*, 43 LOYOLA L. A. L. REV. 785, 798 (2010) (citing three Federal Circuit decisions from within the past ten years).

in the art to which it pertains, or with which it is most nearly connected, to make and use the same.”³⁸

“To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation.’”³⁹ The enablement requirement is satisfied if a person having ordinary skill in the art (“PHOSITA”) can practice the invention based on the teachings of the patent without undue experimentation.⁴⁰ “The determination of what constitutes *undue* experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art.”⁴¹ Enablement is a question of law, reviewed on appeal *de novo*, based on underlying findings of fact, which are reviewed on appeal for clear error.⁴²

The (separate) written description requirement has two main purposes: (1) “to ensure that the inventor has possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him”⁴³ and (2) to ensure that the inventor sufficiently discloses “what the invention is.”⁴⁴ In the first instance, this requirement typically operates to ensure that inventors cannot “improperly amend their patents by including subsequent technical advances in a previously filed application.”⁴⁵ That is, inventors cannot claim that a previously filed patent application covers inventions that either the inventor or a third party developed after filing the previously filed patent application.⁴⁶ Thus, the written description requirement “serves both to satisfy the inventor’s obligation to disclose the technology knowledge upon which the patent is based and to demonstrate

38. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1367 (Fed. Cir. 2010) (Linn, J., dissenting-in-part and concurring-in-part) (citation and quotation omitted).

39. *ALZA Corp. v. Andrx Pharms., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010) (citation and quotation omitted); see also *ADELMAN*, *supra* note 25, at 386.

40. *ALZA Corp.*, 603 F.3d at 940 (“Enablement is not precluded where a ‘reasonable’ amount of routine experimentation is required to practice a claimed invention, however, such experimentation must not be ‘undue.’” (citations omitted)).

41. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (emphasis added).

42. *E.g.*, *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1369 (Fed. Cir. 1999) (“Whether undue experimentation would have been required to make and use an invention, and thus whether a disclosure is enabling under 35 U.S.C. § 112, ¶ 1, is a question of law that we review *de novo*, based on underlying factual inquiries that we review for clear error.”).

43. *In re Alton*, 76 F.3d 1168, 1172 (Fed. Cir. 1996) (quoting *In re Wertheim*, 541 F.2d 257, 262 (C.C.P.A. 1976)).

44. *Univ. Of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 922 n.5 (Fed. Cir. 2004).

45. *ADELMAN*, *supra* note 25, at 387.

46. If an inventor came up with a novel improvement to his or her invention, he or she could file a new patent application directed towards the novel improvement.

that the patentee was in possession of the invention that is claimed.”⁴⁷ The written description requirement limits the scope of what an inventor can claim as his own invention to the invention actually disclosed in the specification as of the patent application’s filing date.⁴⁸ Compliance with the written description is a question of fact reviewed on appeal for clear error.⁴⁹

D. *Pre-Federal Circuit Courts of Appeals*

Federal district courts have exclusive original jurisdiction for patent infringement and declaratory judgment (of non-infringement or invalidity or both) lawsuits.⁵⁰ Prior to October 1982, the United States Courts of Appeals had jurisdiction over appeals in patent cases filed in federal district courts.⁵¹ Because cases that were appealed were heard by the a Circuit Court of Appeals based on the geographic location of the district court lawsuit, patent law was interpreted differently in different regions of the country.⁵²

The inconsistency in the application of the law affected patent litigation. Based on statistics in the years 1945–57, “a patent was twice as likely to be held valid and infringed in the Fifth Circuit than in the Seventh Circuit, and almost four times more likely to be enforced in the Seventh Circuit than in the Second Circuit.”⁵³ Unsurprisingly, forum shopping was prevalent,⁵⁴ and patentees and accused infringers would fight bitterly over requests to transfer patent infringement or declaratory judgment actions.⁵⁵ In a legal environment that appeared to be lacking certainty in the rules of patent law, “the promise of a patent

47. *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005).

48. *See Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47, 57 (1938) (“[T]he patent monopoly does not extend beyond the invention described and explained . . . it cannot be enlarged by claims in the patent not supported by the description . . .”).

49. *E.g.*, *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) (“Because of its fact intensive nature, we review a district court’s decision on the adequacy of written description for clear error.” (citation omitted)).

50. Patent disputes are exclusively filed in federal district courts. 28 U.S.C. § 1338(a) (2012) (“The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents. . . . Such jurisdiction shall be exclusive of the courts of the states in patent . . . cases.”).

51. *See* Paul M. Janicke, *To Be or Not to Be: The Long Gestation of the U.S. Court of Appeals for the Federal Circuit (1887-1982)*, 69 ANTITRUST L.J. 645, 645-46 (2001).

52. Dreyfuss, *supra* note 9, at 6.

53. *Id.* at 7 (citing Cooch, *The Standard of Invention in the Courts*, in DYNAMICS OF THE PATENT SYSTEM 34, 56–59 (W. Ball ed. 1960)).

54. Dreyfuss, *supra* note 9, at 7.

55. *See, e.g.*, *Hoffman v. Blaski*, 363 U.S. 335, 336-44 (1960).

could hardly be considered sufficient incentive to invest in research and development.”⁵⁶ The Supreme Court of the United States rarely stepped in to provide guidance. Some scholars have suggested that “increasing demands on its docket and a general perception by the judiciary that patent cases were particularly troublesome or difficult” caused this void.⁵⁷ This set the stage for the creation of a single appellate forum for patent disputes.⁵⁸

E. Specialized Courts

Judge Learned Hand was fascinated by the idea of “technical judges to whom technical questions are submitted and who can intelligently pass upon the issues without blindly groping among testimony upon matters wholly out of their ken.”⁵⁹ Specialized courts—tribunals that deal with “all cases of a particular sort”⁶⁰—have been an attractive idea to many who believe that specialized courts would improve judicial results, efficiency, and stability.⁶¹ Although the Supreme Court could act as a single tribunal for patent appeals to provide “better guidance” and “reduce opportunistic litigation strategies such as forum shopping,” the Supreme Court is simply not able to hear enough cases to succeed in this capacity.⁶²

In contrast, skeptics of specialized courts have identified several potential dangers. One concern is that such courts will have “tunnel vision, with judges who are overly sympathetic to the policies furthered by the law that they administer or who are susceptible to ‘capture’ by the bar that regularly practices before them.”⁶³ Another is that “judges [will be] vulnerable to lobbyists and their positions will be susceptible to ideological appointments” because of “[t]he one-dimensional nature of the docket.”⁶⁴

56. Dreyfuss, *supra* note 9, at 7.

57. Wagner & Petheridge, *supra* note 11, at 1115 (citing Charles W. Adams, *The Court of Appeals for the Federal Circuit: More than a National Patent Court*, 49 MO. L. REV. 43, 45; Dreyfuss, *supra* note 9, at 6).

58. Dreyfuss, *supra* note 9, at 7.

59. *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 115 (C.C.S.D.N.Y. 1911) *aff'd in part, rev'd in part sub nom.* *Parke-Davis & Co. v. H.K. Mulford & Co.*, 196 F. 496 (2d Cir. 1912).

60. Dreyfuss, *supra* note 9, at 2.

61. *See id.* (“[Supporters of specialized courts] believe that if all cases of a particular sort were channelled to a single tribunal, that forum would use its monopoly to inject doctrinal stability into the law it administers.” (footnote omitted)).

62. *Id.*

63. *Id.* at 3 (citation omitted).

64. *Id.* (citation omitted).

Despite the possible dangers of creating a specialized court, Congress established the Court of Appeals for the Federal Circuit when it passed the Federal Courts Improvement Act (FCIA) in 1982.⁶⁵ This began what has been described as “a sustained experiment in specialization.”⁶⁶ Since its foundation in 1982, the Federal Circuit has been the exclusive venue for appeals in the majority of patent disputes.⁶⁷

F. *The Court of Appeals of the Federal Circuit*

By appointing the Federal Circuit as the exclusive forum for patent appeals from federal district courts and from the PTO, Congress sought to eliminate—or at least minimize—unfairness and inconsistency in the application of patent law.⁶⁸ In essence, the Federal Circuit’s formation combined the Court of Customs and Patent Appeals (CCPA), which heard appeals from the United States Customs Court and from the PTO,⁶⁹ with the Court of Claims, which had been the principal forum for all claims against the federal government.⁷⁰ Even though the Federal Circuit has appellate jurisdiction in areas such as “trademark, tariff and customs law, technology transfer regulations, and government contract and labor disputes,”⁷¹ the Federal Circuit is likely best known for its patent law jurisprudence.⁷²

G. *Patent Law and Technical Backgrounds*

There is a longstanding association between patent law and technical training or education.⁷³ For example, the PTO requires an individual to “[possess] the legal, scientific, and technical qualifications necessary for him or her to render applicants valuable service” before

65. Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (codified as amended in scattered sections of 28 U.S.C.).

66. Dreyfuss, *supra* note 9, at 3.

67. *See id.* at 3-4.

68. *Id.* at 7.

69. *History of the Federal Judiciary: U.S. Court of Customs and Patent Appeals (successor to the Court of Customs Appeals), 1910-1982*, FEDERAL JUDICIAL CENTER, http://www.fjc.gov/history/home.nsf/page/courts_special_cpa.html (last visited Jul. 3, 2012).

70. *History of the Federal Judiciary: Court of Claims, 1855-1982*, FEDERAL JUDICIAL CENTER, http://www.fjc.gov/history/home.nsf/page/courts_special_coc.html (last visited Apr. 3, 2013).

71. Dreyfuss, *supra* note 9, at 4 (citations omitted).

72. *See id.* at 4-5.

73. W. Michael Schuster, *Claim Construction and Technical Training: An Empirical Study of the Reversal Rates of Technically Trained Judges in Patent Claim Construction Cases*, 29 QUINNIPIAC L. REV. 887, 900-01 (2011).

an individual may register to practice before the PTO.⁷⁴ The PTO's *General Requirements Bulletin for Admission to the Examination for Registration to Practice in Patent Cases Before the United States Patent and Trademark Office* delineates qualifications that are necessary to render this valuable service.⁷⁵ There are three main routes by which a party can demonstrate sufficient scientific and technical training to practice before the PTO: (1) by earning a Bachelor's Degree in a recognized technical subject;⁷⁶ (2) by earning a Bachelor's Degree in another (non-technical) subject but with sufficient scientific education;⁷⁷ or (3) by relying on practical engineering or scientific experience and passing the Fundamentals of Engineering test.⁷⁸

Although the PTO has this requirement for technical qualifications,⁷⁹ federal judges who hear patent cases are *not* required to have technical backgrounds. Despite the lack of a technical background requirement, fourteen district courts have recently started participating in a Patent Pilot Program.⁸⁰ Under this program, a judge may decline to accept a patent case if he or she is not among the judges designated to hear such cases.⁸¹ If a judge elects to do so, the patent case will be randomly assigned to one of the district judges designated to hear patent cases.⁸²

Similar to federal district court judges, Federal Circuit judges are not required to have technical qualifications in order to hear patent cases. For the purposes of the present study, Federal Circuit judges were classified as "technical" or "non-technical" using the first and third categories that are used to show sufficient technical expertise to

74. 37 C.F.R. § 11.7(a)(2)(ii) (2011).

75. Schuster, *supra* note 73, at 901 (citing U.S. PATENT & TRADEMARK OFFICE, GENERAL REQUIREMENTS BULLETIN FOR ADMISSION TO THE EXAMINATION FOR REGISTRATION TO PRACTICE IN PATENT CASES BEFORE THE UNITED STATES PATENT TRADEMARK OFFICE 4-8 (2011), available at <http://www.uspto.gov/web/offices/dcom/olia/oed/grb.pdf>).

76. U.S. PATENT & TRADEMARK OFFICE, GENERAL REQUIREMENTS BULLETIN FOR ADMISSION TO THE EXAMINATION FOR REGISTRATION TO PRACTICE IN PATENT CASES BEFORE THE UNITED STATES PATENT TRADEMARK OFFICE 4-5 (2011), available at <http://www.uspto.gov/web/offices/dcom/olia/oed/grb.pdf>.

77. *Id.* at 5-8.

78. *Id.* at 8.

79. Because patent examiners are required to have technical qualifications, one would assume that BPAI judges are required to have technical qualifications. It is unclear from the PTO website alone whether this is true.

80. *District Courts Selected for Patent Pilot Program*, UNITED STATES COURTS, [http://www.uscourts.gov/news/newsview/11-06-](http://www.uscourts.gov/news/newsview/11-06-07/District_Courts_Selected_for_Patent_Pilot_Program.aspx)

07/*District_Courts_Selected_for_Patent_Pilot_Program.aspx* (June 7, 2011).

81. *Id.*

82. *Id.*

practice before the PTO (as described above). It was certainly conceivable that one or more of the Federal Circuit judges classified as “non-technical” in the present study would have been better classified as “technical,”⁸³ but without further information to substantiate the judges’ technical expertise, it is assumed that these judges have been classified correctly as having “non-technical” backgrounds.

H. Purpose of Empirical Study

This empirical study aims to determine whether having a technical background affects Federal Circuit judges’ analysis of the Section 112 enablement and written description requirements. In particular, this study will focus on whether Federal Circuit judge panels comprising a majority of technical judges are more likely to invalidate patents or reverse lower court decisions, whether the invalidation and reversal rates change depending on the lower court’s decision, whether the level of deference is different for enablement as compared to written description cases, and whether the invalidation and reversal rates have changed as a function of time over the past fifteen years. Also of interest is whether the Federal Circuit uses a noticeably different analysis for Section 112 issues arising from district court decisions rather than decisions of the PTO Board of Appeals and Interferences (BPAI),⁸⁴ whether biotechnology patents have a higher standard of enablement and written description compared to other technical areas, and whether, in recent years, the Federal Circuit has treated the enablement and written description requirements as being distinct and separate requirements.

Several empirical studies have scrutinized claim construction reversal rates in patent cases.⁸⁵ These studies have shown a lack of cor-

83. For example, one or more of the Federal Circuit judges who have a Bachelor’s Degree in a non-technical subject may have taken a sufficient number of semester hours in scientific or engineering courses to satisfy the PTO’s requirement for scientific and technical qualifications.

84. “The Board of Patent Appeals and Interferences shall, on written appeal of an applicant, review adverse decisions of examiners upon applications for patents and shall determine priority and patentability of invention in interferences. . . .” 35 U.S.C. § 6(b) (2012). The BPAI’s primary responsibilities include reviewing (1) *ex parte* appeals from adverse decisions of examiners in those situations where a written appeal is taken by a dissatisfied patent applicant and (2) interferences to “determine priority” (that is, decide who is the first inventor) whenever an applicant claims the same patentable invention which is already claimed by another applicant or patentee. Board of Patent Appeals and Interferences, USPTO.GOV, <http://www.uspto.gov/ip/boards/bpai/index.jsp> (last visited Apr. 3, 2013).

85. See David L. Schwartz, *Practice Makes Perfect? An Empirical Study of Claim Construction Reversal Rates in Patent Cases*, 107 MICH. L. REV. 223 (2008); Wagner & Petheridge, *supra* note 11

relation between reversal rates in claim construction and either judges' experience in patent cases⁸⁶ or judges' undergraduate education in technical subjects.⁸⁷ An empirical study that focused specifically on the Federal Circuit's claim construction analysis found a strong dependency between the judges on a particular panel and the panel's approach to claim construction.⁸⁸

The present study is the first empirical study focused specifically on how Federal Circuit judges interpret and apply the Section 112 enablement and written description requirements, and whether the technical background of these judges correlates with their interpretation and analysis of these requirements.

II. EMPIRICAL STUDY DESIGN

The present study aims to determine whether there is a correlation between the technical education of Federal Circuit judges and their analysis of Section 112 enablement and written description requirements by examining such statistics as invalidation rate and reversal rate.

A. *Classifying Judges as Technical (T) or Non-Technical (N)*

Each Federal Circuit judge was classified as having a technical (T) or non-technical (N) background, based primarily on his or her university education, but also taking into account whether the judge had any relevant work or research experience.⁸⁹ Accordingly, seven judges were classified as having technical backgrounds:⁹⁰

(focusing specifically on the Federal Circuit's claim construction analysis); Schuster, *supra* note 73.

86. Schwartz, *supra* note 85, at 255-56.

87. Schuster, *supra* note 73, at 920.

88. Wagner & Petheridge, *supra* note 11, at 1165-70.

89. Although the present study was limited to the period 1997-2011, each judge from the beginning of the Federal Circuit was categorized as either "technical" or "non-technical." Even though Chief Judge Randall Rader has previously taught patent law as a full-time professor and has co-authored one of the preeminent casebooks in the field of patent law, he was classified as "non-technical" for the purposes of the present study. *The Court, Judges*, U.S. COURT OF APPEALS FOR THE FED. CIRCUIT, <http://www.cafc.uscourts.gov/judges/> (last visited Apr. 3, 2013).

90. See *History of the Federal Judiciary: U.S. Court of Appeals for the Federal Circuit*, FEDERAL JUDICIAL CENTER, <http://www.fjc.gov/servlet/nGetCourt?cid=17&order=a&ctype=ac&instate=fc> (last visited Apr. 3, 2013); *The Court, Judges*, *supra* note 89.

Judge	Relevant Technical Experience	Federal Circuit Term of Service
Judge Kimberly Moore	B.S.E.E., Electrical Engineering M.S., Electrical Engineering	2006–present
Judge Richard Linn	B.E.E., Electrical Engineering Former patent examiner	1999–present
Judge Arthur Gajarsa	B.S.E.E., Electrical Engineering Former patent examiner	1997–2011 2011–present (Senior Circuit Judge)
Judge Alan Lourie	M.S., Organic Chemistry Ph.D., Chemistry Research Chemist, Monsanto Corp. Scientist, Chemist, Patent Agent, Wyeth Labs	1990–present
Judge Pauline Newman	Master's, Pure Science Ph.D., Chemistry Research Scientist, American Cynamid Co.	1984–present
Judge Giles Rich	Former patent attorney (for 27 years) Helped to draft 1952 Patent Act	1982–1999
Judge Howard Markey	B.A./J.D. in patent law Former patent attorney	1982–1991

Because Judges Sharon Prost, Haldane Mayer, Jean Bissell, and Shiro Kashiwa each had a Bachelor of Science degree in an unknown subject,⁹¹ they were each assumed to have non-technical backgrounds.⁹² The remaining twenty-three judges⁹³ were each classified

91. These unknown Bachelor of Science degrees were assumed to be in non-technical subjects.

92. The terms of service of these four judges are: Judge Sharon Prost (2001–present), Judge Haldane Mayer (1987–2010; 2010–present as Senior Circuit Judge), Judge Judges Jean Bissell (1984–1990), and Shiro Kashiwa (1982–1986).

93. The twenty-three Federal Circuit judges with non-technical backgrounds (and terms of service) are Judges Evan Wallach (2011–present), Jimmie Reyna (2011–present), Kathleen O'Malley (2010–present), Timothy Dyk (2000–present), William Bryson (1994–present), Alvin Schall (1992–2009; 2009–present as Senior Circuit Judge (SCJ)), Randall Rader (1990–present), Raymond Clevenger (1990–2006; 2006–present as SCJ), Sheldon Plager (1989–2000; 2000–present as SCJ), Paul Michel (1988–2010), Glenn Archer (1985–1997), Daniel Friedman (1982–1989; 1989–2011 as SCJ), Edward Smith (1982–1989; 1989–2011 as SCJ), Byron Skelton (1982–

as having non-technical backgrounds. All of these judges had B.A. or A.B. degrees—except for Judges James Almond and Arnold Cowen, who each had a L.L.B. degree—and no relevant work experience as patent attorneys, patent agents, patent examiners, or research scientists.⁹⁴ Overall, seven judges were classified as having technical (T) backgrounds and twenty-seven judges were classified as having non-technical (N) backgrounds.

In addition to the thirty-four Federal Circuit judges, there were eleven federal district court judges featured in the present study who were sitting by designation⁹⁵ in one or more cases before the Federal Circuit (including one—Judge O'Malley—who was later appointed to the Federal Circuit).⁹⁶ Each of these judges had a Bachelor of Arts degree.⁹⁷ Five judges sitting by designation each had a Master's degree in

2004), Marion Bennett (1982–1986; 1986–2000 as SCJ), Philip Nichols (1982–1983; 1983–2000 as SCJ), Helen Nies (1982–1995; 1995–1996 as SCJ), Jack Miller (1982–1985; 1985–1994 as SCJ), Phillip Baldwin (1982–1986; 1986–1991 as SCJ), Don Laramore (1982–1989 as SCJ), Oscar Davis (1982–1988), Arnold Cowen (1982–1987 as SCJ), and James Almond (1982–1986 as SCJ). *History of the Federal Judiciary*, *supra* note 90; *The Court, Judges*, *supra* note 89.

94. See *History of the Federal Judiciary*, *supra* note 90.

95. "Sitting by designation" is the common term for the practice described in 28 U.S.C. § 291(b) (2012).

96. See *Crown Packaging Tech., Inc. v. Ball Metal Beverage Container Corp.*, 635 F.3d 1373, 1375 (Fed. Cir. 2011) ("The Honorable Ronald M. Whyte, United States District Court for the Northern District of California, sitting by designation."); *Yorkey v. Diab*, 605 F.3d 1297, 1298 n.1 (Fed. Cir. 2010) ("Hon. Virginia M. Kendall, U.S. District Court for the Northern District of Illinois, sitting by designation."); *Yorkey v. Diab*, 601 F.3d 1279, 1280 n.1 (Fed. Cir. 2010) (Judge Kendall sitting by designation); *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1345 n.1 (Fed. Cir. 2010) ("Honorable Ron Clark, District Judge, United States District Court for the Eastern District of Texas, sitting by designation."); *Agilent Techs, Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1368 (Fed. Cir. 2009) ("The Honorable Richard A. Posner, Circuit Judge, United States Court of Appeals for the Seventh Circuit, sitting by designation."); *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 563 F.3d 1358, 1362 (Fed. Cir. 2009) (Judge Posner sitting by designation); *Cordis Corp. v. Boston Scientific Corp.*, 561 F.3d 1319, 1323 (Fed. Cir. 2009) ("Honorable Marilyn L. Huff, District Judge, United States District Court for the Southern District of California, sitting by designation."); *Hyatt v. Dudas*, 551 F.3d 1307, 1308 (Fed. Cir. 2008) ("Honorable T. John Ward, District Judge, United States District Court for the Eastern District of Texas, sitting by designation."); *In re Alonso*, 545 F.3d 1015, 1017 (Fed. Cir. 2008) ("Honorable Richard G. Stearns, District Judge, United States District Court for the District of Massachusetts, sitting by designation."); *Pharm. Res., Inc. v. Roxane Labs., Inc.*, 253 F. App'x 26, 27 (Fed. Cir. 2007) ("Honorable Denise Cote, United States District Judge for the Southern District of New York, sitting by designation."); *Adang v. Umbeck*, No. 2007-1120, 2007 WL 3120323 (Fed. Cir. Oct. 25, 2007) ("Honorable Irene M. Keeley, Chief Judge, United States District Court for the Northern District of West Virginia, sitting by designation."); *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1354 (Fed. Cir. 2007) ("Honorable Kathleen O'Malley, District Judge, United States District Court for the Northern District of Ohio, sitting by designation."); *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1364 (Fed. Cir. 2007) ("Honorable Patti B. Saris, District Judge, United States District Court for the District of Massachusetts, sitting by designation.");

97. Each judge's background was viewed by searching for the judges on Federal Judicial Center, *History of the Federal Judiciary*, *supra* note 90.

addition to a Bachelor's degree.⁹⁸ Based on this information, each of the eleven district court judges sitting by designation was classified as having a non-technical (N) background.

B. Measurement Criteria for Study

Each of the relevant cases had its relevant corresponding data collected in a spreadsheet. The data collected for the study from each case comprised:⁹⁹

- (a) Case name
- (b) Citation
- (c) Year that opinion issued
- (d) 35 U.S.C. § 112 issue (enablement/written description/both)
- (e) Lower court
- (f) Lower court's result with respect to Section 112
- (g) Federal Circuit's result with respect to Section 112
- (h) Panel/en banc decision
- (i) Procedural history (JMOL or merits; summary judgment; appeal from BPAI)
- (j) Panel judges (names)
- (k) Technical background of panel¹⁰⁰
- (l) Authoring judge (name)
- (m) Technical background of authoring judge
- (n) Judge(s) concurring or dissenting in the opinion (names)
- (o) Technical background of dissenting judge
- (p) Subject matter of patent
- (q) Is the written description requirement separate from the enablement requirement?
- (r) If written description was at issue, was the Section 112 written description issue related to the earliest available filing date?
- (s) If BPAI, was the case appealed by patentee because of a denied application or did the case arise via an interference proceeding?

98. *Id.*

99. Although data on the required level of experience for a PHOSITA was initially part of the present study, this data collection proved too arduous—the Federal Circuit decision (and typically the lower court decision, too) would rarely, if ever, discuss the relevant level of a PHOSITA in its opinion. If there was a way to readily determine the level of a PHOSITA in each case, perhaps from trial documents, it could prove to be a valuable addition to a similar empirical study.

100. The judges' technical backgrounds were determined primarily based upon each judge's educational background. In the present study, each judge was classed as either "T" for "Technical" or "N" for "Nontechinal." In a future study, it could be worth expanding this categorization beyond a binary approach to take into account higher technical degrees (such as a Master's or a doctorate) or practical patent law experience.

It was important to collect the case names and citations for identification purposes. The year of the opinion was extremely important in assessing the changes in the Section 112 analysis with respect to time. Cases were identified as involving the written description requirement, the enablement requirement, or both. The lower court, its corresponding decision, and the Federal Circuit's decision were all essential for examining the level of deference given by the Federal Circuit. The names of the judges on the panel, the authoring judge, any joining judges, and any dissenting judges were important for identifying possible factions and identifying the technical background of the panels. Analyzing the technical backgrounds of the judges provided an insight as to whether judges who had practiced patent law or studied science as undergraduate or graduate students approached Section 112 issues differently from their colleagues who had backgrounds in liberal arts. The subject matter was identified as potentially important for determining whether the judges treated the Section 112 requirements consistently across different technical areas. Because the severability of the written description requirement from the enablement requirement has continued to be an issue throughout the existence of the Federal Circuit, it was considered worth analyzing. Because written description issues tended to fall into two distinct categories—there was a dispute over either the earliest available filing date, or whether the specification adequately described the invention—this was an easy variable to measure.¹⁰¹ Because BPAI cases were appealed either by a patentee who had his patent application rejected or from an interference proceeding, this variable was also measured.

C. *Locating Cases*

A fairly crude, but effective, search method was used to find cases from the Federal Circuit from the past fifteen years that focused on Section 112 enablement or written description issues. Federal Circuit cases were found by searching,¹⁰² using the search parameters “112 and ATLEAST5(enable!) or ATLEAST5(“written description”)” limited to dates between “01/01/1997” and “12/31/2011” within the search

101. In addition, this could provide insights as to why the Federal Circuit is less deferential in some written description areas than in others.

102. WestlawNext™ was used to search for cases. The present article has not been authorized, sponsored, or otherwise approved by Westlaw® or LexisNexis® or any related companies or subsidiaries. The use of these products is mentioned simply to clarify how cases were located during the present study.

database of “Federal Circuit.”¹⁰³ Even though this search technique was over-inclusive by capturing a good number of cases—202 of 365 cases—that did not discuss the enablement or written description requirements,¹⁰⁴ these extraneous cases were readily excluded from the analysis and thus did not affect the results of the study.¹⁰⁵ Two further cases were excluded on different grounds.¹⁰⁶ Thus, the study focused on the remaining 161 cases,¹⁰⁷ all of which substantively involved Section 112 enablement or written description issues.

In contrast to excluding irrelevant cases, it was more difficult to rectify the problem that the search technique was under-inclusive (1) by missing cases that did not mention “written description” or any variant of the word “enable” at least five times, or (2) by failing to identify cases that were decided under Federal Circuit Rule 36 (Judgment of Affirmance Without Opinion).¹⁰⁸ An easy way to capture more cases

103. This search produced 365 cases as of January 30, 2012. Of these 365 cases, 202 were excluded from the study because the opinions focused on different issues than Section 112 enablement or written description—leaving 163 cases. The same search in Westlaw®—“112 & atleast5(enable!) atleast5(“written description”) & da(aft 1/1/1997 & bef 12/31/2011)” within the database “CTAF”—produced 365 cases as of January 30, 2012. On LexisNexis®, the same search using the search terms “112 AND atleast5(enable!) OR atleast5(“written description”) AND date(geq (1/1/1997) and leq (12/31/2011))” within the Federal Circuit database produced 359 cases as of January 30, 2012. The LexisNexis® cases were not included in the present study because most, and quite possibly all, of the cases would be the same as those identified from the Westlaw® search—although it was conceivable that the LexisNexis® search identified different cases from the Westlaw® search.

104. The search technique described *supra* note 103 captured numerous cases that involved different issues than Section 112 enablement or written description issues (in rare instances, the cases did not even involve patents). Such cases were simply ignored and not included in the present study. In addition, the study excluded any cases that were a denial of a petition for either a rehearing or a rehearing en banc.

105. Most commonly, these extraneous cases were located during the search because the cases either (a) discussed claim construction of means-plus-function claims in light of the written description under Section 112, paragraph 6; or (b) discussed Section 102 enablement and distinguished it from Section 112 enablement.

106. One of the 163 cases—*Honeywell Int’l, Inc. v. United States*, 596 F.3d 800 (Fed. Cir. 2010)—was excluded because it was overruled after a rehearing. *See Honeywell Int’l, Inc. v. United States*, 609 F.3d 1292 (Fed. Cir. 2010). One of the remaining 162 cases was excluded—*Mycogen Plant Science, Inc. v. Monsanto Co.*, 252 F.3d 1306 (Fed. Cir. 2001)—because the district court had, on summary judgment, invalidated the patent-in-suit as being obvious and thus had treated the enablement issue as moot. *Mycogen Plant Science, Inc. v. Monsanto Co.*, 252 F.3d 1306, 1317 (Fed. Cir. 2001) (leaving determination of “whether there is a genuine issue of material fact as to enablement” to the district court because resolution of the enablement issue was not clear).

107. Including the reheard *Honeywell Int’l* case (*Honeywell Int’l, Inc. v. United States*, 609 F.3d 1292 (Fed. Cir. 2010)).

108. Rule 36. Entry of Judgment – Judgment of Affirmance Without Opinion
The court may enter a judgment of affirmance without opinion, citing this rule, when it determines that any of the following conditions exist and an opinion would have no precedential value: (a) the judgment, decision, or order of the trial court appealed from is based on findings that are not clearly erroneous;

would be to reduce the ATLEAST variables to four or fewer, but this would generate a greater number of false positives.¹⁰⁹ Based on an initial pilot search, five was selected as an appropriate number for the ATLEAST variable, because it generated a manageable number of false positives. The results of the present study should be interpreted knowing that there may be a possible bias created by failing to include Rule 36 cases. Including Rule 36 cases would likely provide a more accurate statistic of how often the lower courts' decisions are reversed; the reversal rate would almost certainly drop, because all cases decided by the Federal Circuit under Rule 36 involve affirmances of a lower court's decision.

D. Calculating the Reversal Rate and the Patent Invalidation Rate

The percentage "reversal rate" (R_R) was calculated by the following equation:

$$R_R = \frac{N_R}{N_D} \times 100$$

where N_R is the number of cases in which the decision of the lower court on the Section 112 enablement or written description issue was reversed or vacated and N_D is the total number of cases decided (i.e., N_D equals N_R plus the number of cases in which the decision of the lower court on the Section 112 enablement or written description issue was affirmed).

The percentage "patent invalidation rate" (R_I) was calculated by the following equation:

$$R_I = \frac{N_I}{N_{112}} \times 100$$

where N_I is the total number of cases in which the patent was invalidated for failure to comply with the Section 112 enablement or written description requirements and N_{112} is the number of cases in

(b) the evidence supporting the jury's verdict is sufficient;

(c) the record supports summary judgment, directed verdict, or judgment on the pleadings;

(d) the decision of an administrative agency warrants affirmance under the standard of review in the statute authorizing the petition for review; or

(e) a judgment or decision has been entered without an error of law.

United States Court of Appeals for the Federal Circuit, Rules of Practice, 77-78, <http://www.cafc.uscourts.gov/images/stories/rules-of-practice/rules.pdf>.

109. Changing the "ATLEAST" number to four generated 397 cases; to three generated 470 cases; to two generated 584 cases, and removing the "ATLEAST" requirement generated 755 cases. Although a number of these extra cases could have been relevant to the present study, it is considerably more likely that the cases merely *mentioned* enablement or written description, rather than *discussing* an enablement or written description issue.

which the Federal Circuit reached the merits of the Section 112 issue (i.e., N_{112} equals N_I plus the number of cases in which the patent was not invalidated for failure to comply with the Section 112 enablement or written description requirements). Based on these definitions of N_I and N_{112} , the following categories of cases were excluded from the invalidation rate calculation:

- fifteen (15) cases in which the Federal Circuit vacated or reversed a lower court's grant of summary judgment because a genuine issue of material fact precluded summary judgment;¹¹⁰
- five (5) cases in which the Federal Circuit invalidated the patent on other grounds so that the enablement or written description issue was moot;¹¹¹ and
- three (3) cases in which the Federal Circuit did not reach the merits of the written description or enablement issue because the lower court had applied the law incorrectly.¹¹²

Eliminating these 23 cases left 138 cases that were used to calculate the overall patent invalidation rate.

E. Classifying the Technical Expertise of Each Panel

Each three-judge panel was classified as either NNN, NNT, NTT, or TTT based on the technical backgrounds of each judge on the panel.¹¹³ The two en banc decisions included in the present study featured NNNNTTTT¹¹⁴ and NNNNNNTTTT¹¹⁵ panels; and the two decisions with five-judge panels both had NTTTT panels.¹¹⁶ It was assumed that panel assignments are random. Based on the majority composition of the panels, each NNN and NNT panel was classified as "non-technical"

110. See, e.g., *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296, 1313 (Fed. Cir. 2010); *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1348 (Fed. Cir. 2005); *Reiffen v. Microsoft Corp.*, 214 F.3d 1342, 1346 (Fed. Cir. 2000).

111. See, e.g., *In re Clark*, 420 Fed. App'x 994, 997-98 (Fed. Cir. 2011); *Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found., LP*, 422 F.3d 1378, 1386 (Fed. Cir. 2005); *Mycogen Plant Science, Inc. v. Monsanto Co.*, 243 F.3d 1316, 1337 (Fed. Cir. 2001).

112. See *Capon v. Eshhar*, 418 F.3d 1349, 1360-61 (Fed. Cir. 2005); *Bilstad v. Wakalopoulos*, 386 F.3d 1116, 1127 (Fed. Cir. 2004); *Southwest Software, Inc. v. Harlequin Inc.*, 226 F.3d 1280, 1299 (Fed. Cir. 2000).

113. The idea for classifying each of the panels in this way was inspired by Professor Cass Sunstein *et al.*'s classification of federal judges on three-judge panels as Republican (R) or Democrat (D), which produced panels that were either RRR, RRD, RDD, or DDD. See Cass R. Sunstein, David Schkade, & Lisa Michelle Ellman, *Ideological Voting on Federal Courts of Appeals: A Preliminary Investigation*, 90 VA. L. REV. 301, 329-30 (2004).

114. See *Hyatt v. Kappos*, 625 F.3d 1320, 1322 (Fed. Cir. 2010) (en banc).

115. See *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1339 (Fed. Cir. 2010) (en banc).

116. See *Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1340 (Fed. Cir. 2011); *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1366 (Fed. Cir. 2009).

(0); and each NTT, TTT, and NTTTT panel was classified as “technical” (1). The two en banc decisions were excluded from characterization as either “non-technical” or “technical.”¹¹⁷

F. Statistical Analysis

Pearson’s chi-squared (χ^2) test was used to test the statistical significance of the results.¹¹⁸ The present study used the 95% confidence interval, such that the true value of the measured parameter is 95% likely to be within the stated range.¹¹⁹ Pearson’s chi-squared test was selected because it is more skeptical than a 1- or 2-tailed t-test.¹²⁰

III. EMPIRICAL STUDY RESULTS

A. Reversal Rate and Patent Invalidation Rate Broken Down into Enablement and Written Description Cases

As discussed in Part II, there were 161 cases included in the present study, 138 of which reached the merits of the Section 112 issue.¹²¹ Figure 1 shows the reversal and patent invalidation rates for all of the cases in the study, broken down by the Section 112 requirement that was at issue in the case. Initially, it is worth noting that the overall reversal rate measured in this study (32.9%) is considerably higher than the overall reversal rate of the Federal Circuit measured by Professor David Schwartz in a separate study (13%, based on data from the years 2004–06).¹²² The overall reversal rate of 32.9% is also considerably higher than the average reversal rate across all issues reported by Professor Ted Sichelman (21%, based on data from the years 2000–07).¹²³

117. Where this characterization was used during the analysis, the two en banc decisions were excluded.

118. The statistical analysis was performed using Rags Srinivasan’s “Statistical Significance Calculator,” available at <http://www.kaushik.net/avinash/excellent-analytics-tip1-statistical-significance/> (last visited Apr. 3, 2013).

119. Schuster, *supra* note 73, at 907 (citing TIMOTHY C. URDAN, STATISTICS IN PLAIN ENGLISH 67 (2d ed. 2005); DAVID S. MOORE & GEORGE P. MCCABE, INTRODUCTION TO THE PRACTICE OF STATISTICS 420 (4th ed. 2003)).

120. Avinash Kaushik, *Excellent Analytics Tip#1: Statistical Significance*, <http://www.kaushik.net/avinash/excellent-analytics-tip1-statistical-significance/> (last visited Apr. 3, 2013).

121. Because a number of cases involved both enablement and written description issues, these cases are counted for both enablement cases and written description cases.

122. Schwartz, *supra* note 85, at 249 (“[T]he Federal Circuit’s overall reversal rate of district court judgments (which are over 95% patent cases) was 13% for each of the years 2004, 2005, and 2006.” (citations omitted)).

123. Ted Sichelman, *Myths of (Un)Certainty at the Federal Circuit*, 43 LOY. L.A. L. REV. 1161, 1175 (2010).

The primary cause of this discrepancy is likely to be the present study's exclusion of cases that were affirmed under Federal Circuit Rule 36.¹²⁴ Professor Schwartz and Professor Sichelman each included cases that were affirmed under Rule 36.¹²⁵ A less persuasive explanation is that Federal Circuit judges are more likely to reverse a lower court's decision regarding a Section 112 requirement because they disagree with how district court judges are applying the Section 112 requirements.

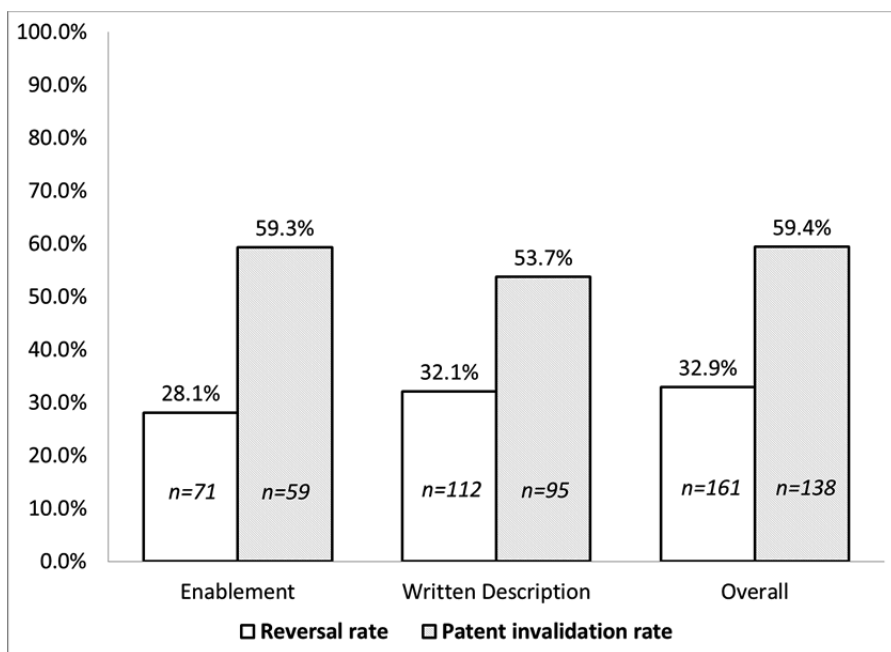


Figure 1— total number of cases broken down by Section 112 requirement at issue.

The reversal rate was similar for enablement (28.1%) and written description (32.1%). Another reason why the overall reversal rate was slightly higher (32.9%) is because the Federal Circuit reversed less often in the twenty-two (22) cases that involved both requirements. These twenty-two cases were included once each in the enablement and written description statistics, but only once in the overall statistics.

124. Rule 36, *supra* note 108.

125. See Schwartz, *supra* note 85, at 238-39; Sichelman, *supra* note 123, at 1174-75.

It is not immediately clear why there would be a lower reversal rate when both requirements were in dispute. One possibility is that in such cases the accused infringer was throwing every possible patent invalidation argument at the wall in the hope that one might stick. Professor Sichelman found reversal rates for written description and enablement issues of 10–15%,¹²⁶ which are considerably lower than the present study's reversal rates of between 28–32%. As discussed above, the most likely explanation is that the present study did not include cases decided under Federal Circuit Rule 36.

The overall patent invalidation rate was 59.4%, slightly higher than the patent invalidation rates for enablement or written description because the Federal Circuit invalidated the patent more often when both requirements were in dispute in the same case. Cases involving both requirements featured once each in the enablement and written description statistics, but only once in the overall statistics. The Federal Circuit was slightly more likely to invalidate patents for failure to comply with the enablement requirement (an invalidation rate of 59.3%) than for failure to comply with the written description requirement (an invalidation rate of 53.7%).¹²⁷ A higher invalidation rate for enablement compared to written description is not surprising given that a finding of enablement is a question of law reviewed *de novo* (albeit with underlying findings of fact that are reviewed for clear error),¹²⁸ whereas compliance with the written description requirement is a question of fact reviewed for clear error.¹²⁹

B. Federal District Courts Compared to the Board of Patent Appeals and Interferences

Figure 2 shows the reversal rate and patent invalidation rate broken down for cases arising on appeal either from one of the federal district courts (DCs) or from the BPAI. The study contained one case arising on appeal from the Court of Federal Claims,¹³⁰ and two cases arising on appeal from the International Trade Commission;¹³¹ each of

126. Sichelman, *supra* note 123, at 1174-75.

127. This finding was not statistically significant.

128. *E.g.*, Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1369 (Fed. Cir. 1999).

129. *E.g.*, Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1330 (Fed. Cir. 2003) (citation omitted).

130. *See* Honeywell Int'l, Inc. v. United States, 609 F.3d 1292, 1294 (Fed. Cir. 2010).

131. *See* Yingbin-Nature (Guangdong) Wood Indus. Co. v. Int'l Trade Comm'n, 535 F.3d 1322, 1325 (Fed. Cir. 2008); Energizer Holdings, Inc. v. Int'l Trade Comm'n, 275 Fed. App'x 969, 971 (Fed. Cir. 2008).

these three cases was grouped with cases arising on appeal from federal district courts.

The reversal rate was significantly higher for cases arising on appeal from federal district courts (38.0%) than from the BPAI (17.5%). This result may indicate that the Federal Circuit judges believe that the BPAI have a better grasp of the Section 112 enablement and written description requirements. Federal Circuit panels were more likely to invalidate patents in cases that reached the Federal Circuit on appeal from the BPAI (a patent invalidation rate of 78.4%) than on appeal from federal district courts (a patent invalidation rate of 52.0%). This result is not surprising given that the majority of the BPAI appeals were filed by patentees whose patent applications were rejected—i.e., the majority of the BPAI appeals arose from denied patent applications, so the patentees who were making the appeals did not enjoy the “presumption of validity” that issued patents enjoy.¹³²

Selection bias may also play a role. Specifically, during litigation the claims tend to be “locked” and need to be defended to death. In contrast, during prosecution, the patent applicant can still modify the claims to overcome rejections. The cases in which the patent applicant chooses to appeal a BPAI decision to the Federal Circuit may be “special cases” in which the applicant did not want to or could not reword the claims to overcome a Section 112 rejection. If selection bias is playing a role, cases arising on appeal from the BPAI are likely extremely different than cases arising on appeal from district courts.

132. 35 U.S.C. § 282 (2012) (“A patent shall be presumed valid.”).

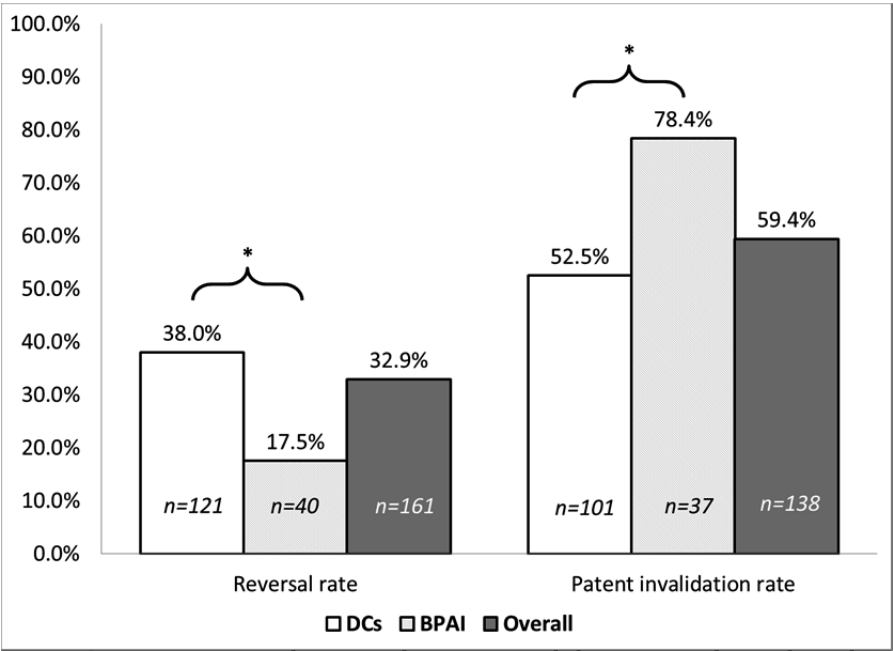


Figure 2—reversal rate and patent invalidation rate for technical and non-technical panels for cases arising from federal district courts (DCs) or the PTO Board of Patent Appeals & Interferences (BPAI). Results marked with a * indicate that the difference in reversal rates or patent invalidation rates between cases arising from DCs or the BPAI was statistically significant ($p < 0.05$) under Pearson’s chi-squared test.

C. Judges’ Technical Backgrounds

Table 1 shows the reversal rate and patent invalidation rate broken down for technical and non-technical panels and further broken down for cases arising on appeal either from one of the federal district courts or from the BPAI. For clarity, Figure 3 shows the overall reversal rates from Table 1. Note that the overall number of cases analyzed has dropped from 161 to 159 because the two en banc cases were excluded from this analysis.¹³³

There was a statistically significant difference between the overall reversal rates of panels composed primarily of technical judges (56.8%) and panels composed primarily of non-technical judges (24.6%). There were also statistically significant differences between the reversal rates of technical and non-technical panels when the re-

133. *Supra* note 117.

sults were broken down between cases arising from federal district courts (technical panel reversal rate of 60.0% versus non-technical rate of 29.2%) and from the BPAI (technical rate of 42.9% versus non-technical rate of 12.1%). This finding suggested that Federal Circuit judges with technical training or expertise are significantly more likely to disagree with a lower court’s decision as to the sufficiency of the patent specification than their Federal Circuit peers with less or no technical training. Federal Circuit judges with technical training may simply believe—consciously or subconsciously—that they “know better” than federal district court judges when analyzing the sufficiency of the patent disclosure. This belief may exist regardless of the technical background of the lower court judge who decided the case that was subsequently appealed.¹³⁴

	Technical Panels			Non-Technical Panels		
	DCs	BPAI	Overall	DCs	BPAI	Overall
Reversal rate	60.0%* (n=30)	42.9%* (n=7)	56.8%* (n=37)	29.2%* (n=89)	12.1%* (n=33)	24.6%* (n=122)
Patent invalidation rate	50.0% (n=24)	83.3% (n=6)	56.7% (n=30)	52.6% (n=76)	77.4% (n=31)	59.8% (n=107)

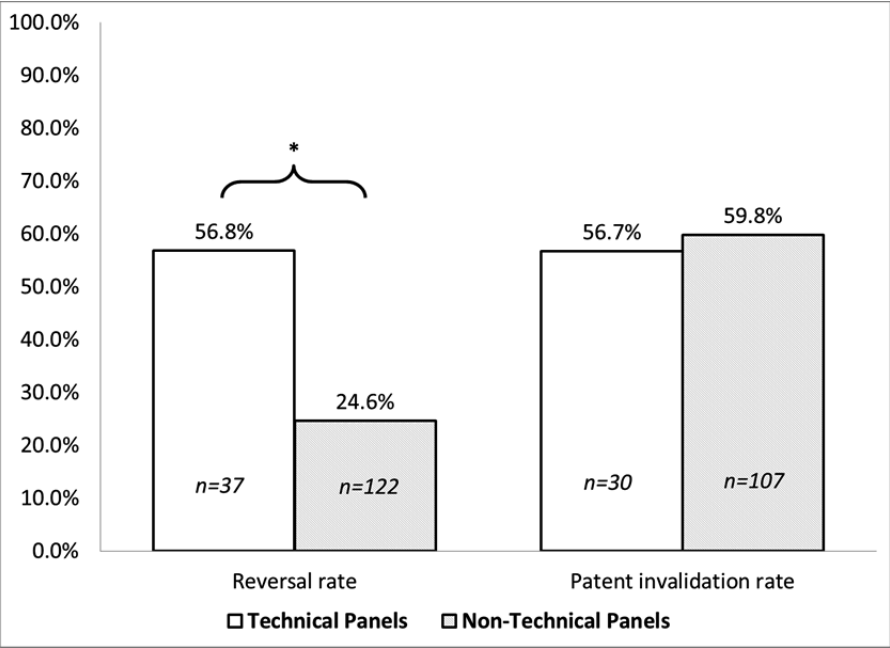
Table 1—reversal rate and patent invalidation rate for technical and non-technical panels for cases arising from federal district courts or the PTO Board of Patent Appeals & Interferences (BPAI). Results marked with a * indicate that the difference in reversal rates between technical and non-technical panels was statistically significant (p < 0.05) under Pearson’s chi-squared test.

An alternative explanation is that technical panels are more inclined to “fiddle.” As part of their “fiddling,” technical panels are likely more inclined to attempt to understand the underlying technology to see whether it complies with the Section 112 requirements. A previous empirical study found that a panel containing a majority of technical judges was much more likely to vacate a lower court decision than a

134. Indeed, previous empirical studies by Professor David Schwartz found a lack of correlation between a judge’s experience with patent cases and his or her propensity to be reversed on appeal. See David L. Schwartz, *Courting Specialization: An Empirical Study of Claim Construction Comparing Patent Litigation Before Federal District Courts and the International Trade Commission*, 50 WM. & MARY L. REV. 1699, 1731-33 (2009); David L. Schwartz, *Practice Makes Perfect? An Empirical Study of Claim Construction Reversal Rates in Patent Cases*, 107 MICH. L. REV. 223, 267 (2008).

non-technical panel, but less likely to reverse a lower court decision.¹³⁵ The apparent discrepancy between a technical panel’s propensity to vacate rather than reverse the BPAI’s decisions in this previous empirical study may be partially attributable to the author’s broad focus on all cases on appeal from the BPAI within a five-year period, rather than cases arising from the BPAI on a specific patent law issue (such as obviousness or the Section 112 requirements).

Figure 3—overall reversal rate and patent invalidation rate for technical and non-technical panels. Results marked with a * indicate that the difference in reversal rates between technical and non-technical panels was statistically significant ($p < 0.05$) under Pearson’s chi-squared test.



Interestingly, technical and non-technical panels were almost equally likely to invalidate a patent (56.7% and 59.8%, respectively). One may have hypothesized that technical panels would be more likely to invalidate patents under Section 112 than non-technical panels be-

135. Thomas Froats, *Unrepresentative Randomization: An Empirical Study of Judging Panels of the USPTO Appeals to the CAFC*, 19 TEX. INTELL. PROP. L.J. 79, 96-97 (2010).

cause they would know the technology better and require a higher standard for sufficiency of disclosure or enablement. Alternatively, technical panels might have been expected to be less likely to invalidate patents because judges with technical backgrounds would be more pro-innovation (and thus pro-patentee) than their less technical peers. The results of the present study marginally agree with the latter hypothesis; technical panels on the Federal Circuit were less likely to invalidate a patent (56.7%) than non-technical panels (59.8%), but this difference was not statistically significant.

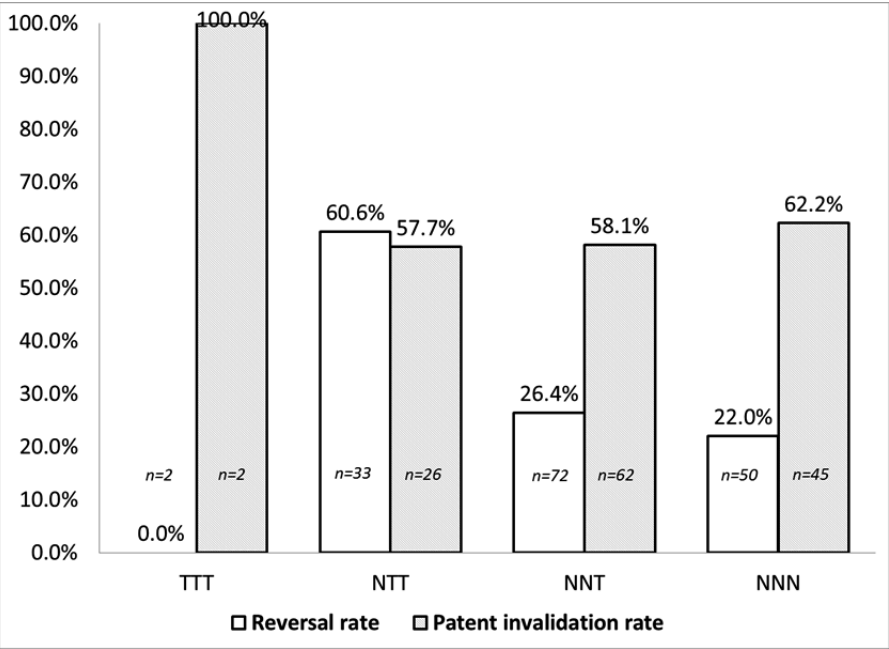


Figure 4— reversal rate and patent invalidation rate for each of the different three-judge panels. The four cases that were decided by more than three judges were excluded from the three-judge panel results.

The result that technical judges were more likely to second-guess lower courts was further underlined by a finding that NTT panels were more likely to reverse or vacate a lower court decision (60.6% of the time) than either NNT panels (30.6% of the time) or NNN panels

(22.0% of the time), as shown in Figure 4. In contrast, TTT panels exhibited a 0.0% reversal rate, but this statistic was based on the results of merely two cases,¹³⁶ one of which arose from the BPAI on an inventor's appeal from a final rejection.¹³⁷ Overall, this finding implies that the propensity of the three-judge panel to reverse may be dominated by the technical or non-technical majority on the panel—i.e. whether two out of three judges have technical expertise (TT-) or not (NN-). A dominating effect on one judge from the other two judges on a three-judge panel has been termed “collegial concurrence” in a study focused on judges’ political ideologies.¹³⁸

In contrast to the reversal rates, the patent invalidation rates of NTT, NNT, and NNN panels were similar, at 57.7%, 58.1%, and 62.2%, respectively. The patent invalidation rate of TTT panels was 100.0%, but again this rate was based on the results of merely two cases.¹³⁹ Excluding the result for the TTT panels, there appeared to be a positive correlation between the technical expertise of a panel and its reluctance to invalidate a patent; but any such correlation was not statistically significant.

C. Reversal Rate When Lower Court Invalidated or Did Not Invalidate

Table 2 shows the reversal rate broken down by whether the lower court invalidated the patent for failure to satisfy either the enablement or the written description requirement, and is further broken down by the technical expertise of the panel. The only statistically significant difference that appeared was between the reversal rate of non-technical panels when deciding a case in which the patent had been invalidated by the BPAI (13.8%) compared to when the patent had not been invalidated by the BPAI (0.0%). Otherwise, the Federal Circuit was generally not more or less likely to reverse a lower court if the lower court had invalidated the patent-in-suit. Technical judges appeared slightly less inclined to reverse a lower court that had invalidated the patent-in-suit (52.2%) than a lower court that had not (64.3%), but this difference was not statistically significant.

136. See *Billups-Rothenberg, Inc. v. Assoc. Regional & Univ. Pathologists, Inc.*, 642 F.3d 1031, 1032 (Fed. Cir. 2011); *In re Lew*, 257 Fed. App'x 281, 281 (Fed. Cir. 2007).

137. *Lew*, 257 Fed. App'x at 284.

138. Sunstein, Schkade & Ellman, *supra* note 113, at 338 (examining federal judges’ political ideology rather than their technical expertise).

139. See *Billups-Rothenberg*, 642 F.3d at 1032; *Lew*, 257 Fed. App'x at 281.

D. Technical Background of Authoring Judge

Figure 5 shows the reversal rate and patent invalidation rate associated with the technical background of the authoring judge, rather than the technical background of the panel on the whole. Per curiam opinions were excluded from this analysis. The reversal rate was significantly higher in opinions authored by a technical judge (47.1%) than in opinions authored by a non-technical judge (23.4%). The patent invalidation rates were comparable for opinions authored by technical judges (55.2%) and non-technical judges (58.2%). These results closely parallel the results for the technical expertise of panels, discussed above in Section C.

E. Two Distinct Written Description Requirement Issues: Possession and Filing Date

The written description requirement issues fell into two broad categories. The first was whether a patentee adequately described the invention in the patent to demonstrate that the inventor was in possession of the claimed invention at the time of filing. The second was whether a patentee should be able to claim priority to the filing date of an earlier filed application from the patent-in-suit.¹⁴⁰ The written description cases were divided into these two categories.

140. Section 120 provides:

An application for patent for an invention disclosed in the manner provided by section 112 . . . in an application previously filed in the United States . . . which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

35 U.S.C. § 120 (2012). Thus, a later patent may only claim priority to an earlier application if the earlier application fulfills the requirements of Section 112, paragraph one. *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1253 (Fed. Cir. 2004).

	Technical Panels			Non-Technical Panels			All Panels		
	DCs	BPAI	Overall	DCs	BPAI	Overall	DCs	BPAI	Overall
Reversal rate (lower court invalidated)	58.8% (n=17)	33.3% (n=6)	52.2% (n=23)	27.7% (n=47)	13.8%* (n=29)	22.4% (n=76)	35.9% (n=64)	17.1% (n=35)	29.3% (n=99)
Reversal rate (lower court did not invalidate)	61.5% (n=13)	100.0% (n=1)	64.3% (n=14)	31.0% (n=42)	0.0%* (n=4)	28.3% (n=46)	38.2% (n=55)	20.0% (n=5)	36.7% (n=60)

Table 2—comparison of reversal rates for when the lower court invalidated the patent-in-suit versus when the lower court did not invalidate the patent-in-suit. Results marked with a * indicate that the difference in reversal rates between cases in which the lower court invalidated and did not invalidate was statistically significant (p < 0.05) under Pearson’s chi-squared test.

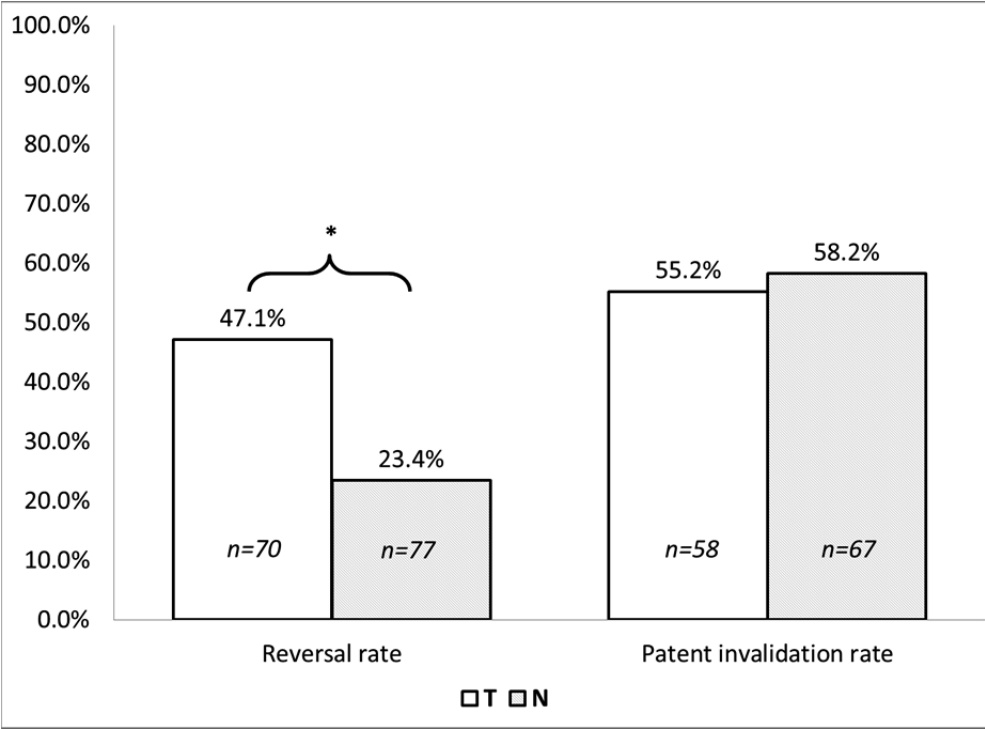


Figure 5—reversal rate and patent invalidation rate and the technical background of the authoring judge. The * indicates that the difference in reversal rates between technical and non-technical

authoring judges was statistically significant ($p < 0.05$) under Pearson's chi-squared test.

Table 3 shows the results from cases involving written description issues. Panels were less likely to reverse lower courts when the issue was whether the patent provided sufficient disclosure to show that the patentee was in possession of the claimed invention (a reversal rate of 28.6%) than when the issue had to do with the earliest filing date that the patentee should be entitled to (a reversal rate of 36.4%). This difference in reversal rates came entirely from cases involving non-technical panels (in which the reversal rate was 21.9% compared to 31.3%), since there was no difference in reversal rates for cases involving technical panels, although the difference only became statistically significant when the cases involving technical panels were included. The fact that the reversal rate was lower for non-technical panels, particularly for cases involving the sufficiency of the written description, suggests once again that non-technical panels are less likely to second guess lower courts.

The patent invalidation rates for these cases showed that three-judge panels were more likely to invalidate patents for failing to show that the patentee was in possession of the invention at the date of application (61.0%) than for claiming a premature filing date (50.9%), although this result was not statistically significant. This difference was stronger for technical panels (80.0% for possession issues compared to 60.0% for filing date issues) than for non-technical panels (54.8% for possession issues compared to 47.5% for filing date issues). These results suggest that technical panels were more likely to require a more detailed written description than non-technical panels.

F. Are Biotechnology Patents More Likely To Be Invalidated Under Section 112?

One might wonder whether the Federal Circuit is more likely to invalidate patents directed towards pharmaceuticals and other biotechnological inventions. For the purposes of this study, "biotechnology patents" included patents directed towards drugs, proteins (including antibodies and enzymes), genes, and genetically modified plants, but did not include patents directed towards medical devices or medical implants. There are several reasons why biotechnology patents might be invalidated more frequently than other patents. First, biotechnology is likely a more unpredictable art than other technical

areas. An inventor falls afoul of the written description requirement if it can be proven that he or she was not in possession of the invention as of the filing date. When describing an invention in an unpredictable art, inventors may claim more broadly than they would otherwise. Second, because biotechnology patents are typically more complicated than patents in other technical areas, there may be a higher hurdle to overcome to satisfy the Section 112 requirements.

Written description issues in biotechnology patent disputes typically hinge on whether the patentee was sufficiently in possession of the particular compound at issue at the time the application was filed.¹⁴¹

	Written D. – filing date			Written D. – sufficient disclosure		
	Overall	T panel	N panel	Overall	T panel	N panel
Reversal rate	36.4%* (n=66)	50.0% (n=18)	31.3% (n=48)	28.6%* (n=42)	50.0% (n=10)	21.9% (n=32)
Patent invalidation rate	50.9% (n=55)	60.0% (n=15)	47.5% (n=40)	61.0% (n=41)	80.0% (n=10)	54.8% (n=31)

Table 3—reversal rate and patent invalidation rate for the two different Section 112 written description issues. Results marked with a * indicate that the difference in reversal rates between the sufficiency of the filing date and the disclosure was statistically significant (p < 0.05) under Pearson’s chi-squared test.

Accused infringers are likely to assert that the patentee is attempting to claim more than he or she actually invented, while the patentee will maintain that he or she possessed the invention on or before the relevant filing date. Similar to satisfying the enablement requirement, inventors may need to provide a greater amount of detail to satisfy the written description requirement for biotechnology patents than for other patents involving other subject matter.

For cases involving biotechnology patents, an enablement issue will often hinge on whether the required level of experimentation is “undue,” because drugs and other chemical compounds may require a large amount of experimentation to produce based purely on the speci-

141. See, e.g., *Univ. Of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 929 n.9 (Fed. Cir. 2004) (“Rochester has claimed a method that could not be adequately described at the time its application was filed.”).

fication.¹⁴² The level of experimentation that is “undue” will vary depending on who the relevant PHOSITA is, and how such a PHOSITA would produce the chemical compound at issue. Therefore, inventors may need to provide a greater amount of detail to satisfy the enablement requirement for biotechnology patents than for patents involving other subject matter.

Figure 6 shows the patent invalidation rate divided up between biotechnology patents and patents involving other subject matter. The results showed that although the patent invalidation rates appeared similar for biotechnology patents (62.5%) and other patents (58.2%), this difference was statistically significant. This finding supports the hypothesis that biotechnology patents have more stringent Section 112 requirements than patents directed towards other subject matter. It remains to be seen whether the higher invalidation rate means that there is a higher enablement or written description standard for biotechnology patents, or that the difference is attributable to the level of unpredictability in the art or another cause.

G. Trends Over Time

Figure 7 shows the Federal Circuit’s reversal rate and patent invalidation rate as a three-year moving average between the years 1997 and 2011 (the fifteen years of the study). There was variation in the reversal rate, from a low of 18.9% in 2006–08 to a high of 46.0% in 2000–02, but no apparent trend in reversal rate with time. Compared to the reversal rate, there was less variation between different years in the rate with which the Federal Circuit invalidated patents for failing to comply with the Section 112 enablement or written description requirements—the invalidation rate remained between below 52.8% and 67.8%—but again there was no apparent trend over time. No conclusions were drawn based upon these results.

H. Separate Enablement and Written Description Requirements

Although this was not a central part of the study, the results from the cases collected indicated that the Federal Circuit consistently treats the Section 112 enablement and written description requirements as

142. The written description must enable a PHOSITA to make and use the invention without “undue experimentation.” *In re Cortright*, 165 F.3d 1353, 1356 (Fed. Cir. 1999).

being two distinct requirements.¹⁴³ The majority of opinions from the past fifteen years that discuss the issue have concluded that enablement and written description are separate statutory requirements.¹⁴⁴ Only a single case—*LizardTech, Inc. v. Earth Resource Mapping, Inc.*¹⁴⁵—contained language in the majority opinion that implied that the Federal Circuit was treating the enablement and written description requirements as a single requirement,¹⁴⁶ but even in this case the authoring judge recognized that the requirements were in fact distinct.¹⁴⁷ Numerous other cases—including the en banc decision in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*¹⁴⁸—explicitly reinforced that the enablement and written description requirements were distinct and separate.¹⁴⁹

143. Even though in many cases it was not clear whether or not the written description and enablement requirements were treated as being separate, there were enough cases (38 cases) within the fifteen year window of the study where the majority did discuss this issue.

144. See, e.g., *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1344 (Fed. Cir. 2010) (en banc); *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 619 F.3d 1329, 1342, 1345 (Fed. Cir. 2010); *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1121 (Fed. Cir. 2008).

145. 424 F.3d 1336 (Fed. Cir. 2005).

146. *Id.* at 1344-45 (explaining that the enablement and written description requirements “usually rise and fall together . . . [because] . . . a recitation of how to make and use the invention across the full breadth of the claim is ordinarily sufficient to demonstrate that the inventor possesses the full scope of the invention, and vice versa.”).

147. *Id.* at 1344 (explaining that section 112 contains “two closely related requirements.”).

148. *Ariad*, 598 F.3d at 1344.

149. *Id.*; see also *In re NTP, Inc.*, 654 F.3d 1268, 1276 (Fed. Cir. 2011); *Eli Lilly & Co.*, 619 F.3d at 1342-45; *Carnegie Mellon*, 541 F.3d at 1121.

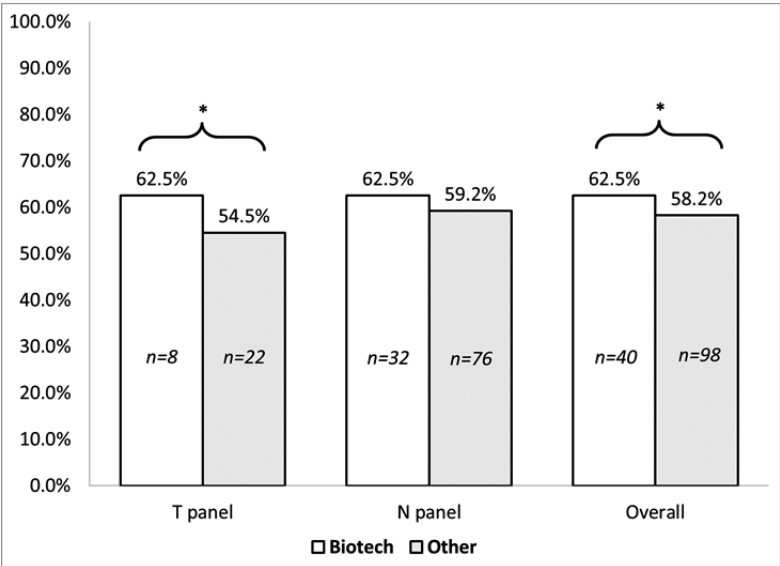


Figure 6—patent invalidation rates (Y-axis) as a function of the subject matter of the patent. Results marked with a * indicate that the difference in patent invalidation rates between biotechnology patents and other patents was statistically significant ($p < 0.05$) under Pearson’s chi-squared test.

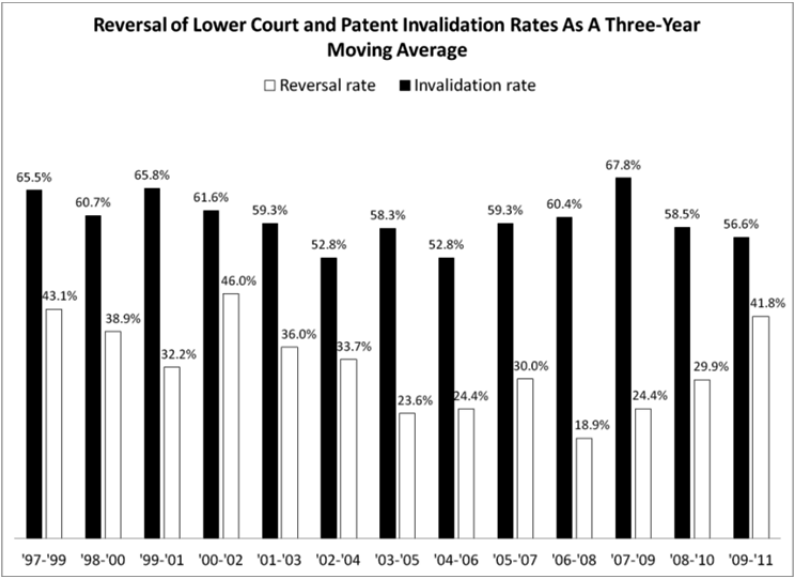


Figure 7—Federal Circuit reversal rate and patent invalidation rate as a three-year moving average as a function of time for Section 112 enablement and written description requirements.

IV. CONCLUSIONS AND STUDY IMPLICATIONS

The results of the present study indicate that technical panels on the Federal Circuit were acting somewhat differently from non-technical panels when dealing with Section 112 enablement and written description issues. In particular, technical panels (and technical authoring judges) were more likely to reverse lower court holdings, whether the appeal was from a federal district court or from the BPAI, and whether or not the lower court had invalidated the patent for failure to comply with Section 112. This interesting finding suggests that technical judges on the Federal Circuit are either (1) more prone than their peers to “fiddle” with lower court decisions; or (2) more dissatisfied than their peers with the way that lower courts are analyzing Section 112 issues. Either of these explanations is plausible; the truth may involve some combination of the two. This finding was, if anything, reinforced when the three-judge panels were further split up and analyzed as NNN, NNT, NTT, and TTT panels. Further, when the authoring judge was technical, the opinion was significantly more likely to involve reversing or vacating the lower court’s decision. There was no significant difference found based upon whether the lower court had invalidated or not invalidated the patent for failure to comply with Section 112.

In contrast to the reversal rate findings, technical and non-technical panels (and technical and non-technical authoring judges) were not significantly more or less likely to invalidate a patent for failure to comply with the Section 112 enablement and written description requirements. Technical panels did not appear to demand a higher patent disclosure standard than non-technical panels. A possible exception was that technical panels were more likely than non-technical panels to invalidate a patent for failing to demonstrate that the inventor was fully in possession of the invention at the time of filing.

Another interesting finding was that patents directed towards biotechnology innovations had a higher patent invalidation rate for failure to satisfy the enablement or written description requirements than patents directed towards other subject matter. This finding has potential implications for patentees (who should be aware that they may need a more detailed disclosure for biotechnology patents), litigators (who may be able to utilize the higher patent invalidation rate when constructing arguments), and judges (who are presumably supposed

to apply the same standard to each patent, even though the subject matter may strongly affect how high the bar to patentability must be raised). This finding may also support the idea that courts are developing different patent rules for patents involving different subject matter.¹⁵⁰

Ultimately, these results could support a call for more judges with technical expertise to be appointed to the Federal Circuit. The current Federal Circuit contains a mix of technical and non-technical judges. Although it is likely beneficial to have diverse backgrounds amongst Federal Circuit judges, it is extremely difficult for the Federal Circuit to coherently promulgate the rules of patent law if the analysis is inconsistent, and it is arguably harder for judges to be consistent when they do not fully grasp the underlying technology. Perhaps a Federal Circuit that primarily contains judges with technical expertise would lead to a more consistent standard. On the other hand, perhaps such a proposal would lead to a Federal Circuit populated by more judges that like to “fiddle,” as suggested by the significantly higher reversal rates found for technical panels in the present study.

Regardless of their technical backgrounds, the Federal Circuit judges are generally in agreement that the written description and enablement requirements are distinct and separate. Moving forward, the Federal Circuit’s focus on written description and enablement requirements is less likely to be on whether the requirements are separate and more likely to be on how much detail is required to satisfy each of the requirements. Ideally, the Federal Circuit could provide detailed and specific instructions about how much detail is sufficient to satisfy Section 112. But in reality, this is extremely unlikely because there is no one-size-fits-all approach for a patent because there is a wide variety of technologies and complexities across the vast range of different inventions that are patented.

150. *See generally* DAN L. BURK & MARK A. LEMLEY, *THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT* (2009).

APPENDIX: CODING INSTRUCTIONS

(a) **Case name.** Text field.

Case name as it appears on Westlaw or Lexis.

(b) **Citation.** Text field.

Legal citation as it appears on Westlaw or Lexis.

(c) **Year.** Numeric field.

Year of case decision as it appears on Westlaw or Lexis.

(d) **Enablement/written description/both.** Variable.

The case analyzed concerns:

0 = enablement under Section 112;

1 = written description under Section 112;

2 = both enablement and written description under Section 112.

(e) **Lower court.** Text field.

Three- or four-letter abbreviation for the name of either (1) the district court, Court of Federal Claims, or International Trade Commission if the case arose via an appeal from one of these courts, or (2) the Board of Patent Appeals and Interferences if the case arose via an appeal from the BPAI.

- If the state contains multiple district courts, the first and second letters are the geographic designation of the district court: ND for Northern District, ED for Eastern District, SD for Southern District, WD for Western District, CD for Central District, and MD for Middle District.
- If the state contains only one district, D is used for the first letter and there is no fourth letter (e.g., DNJ for United States District Court for the District of New Jersey).
- For district courts, the final two letters refer to the state name, as abbreviated by the U.S. Postal Service (e.g., AL for Alabama, AK for Alaska).¹⁵¹ Thus, states with multiple district courts have four-letter abbreviations and states with a single district court have three-letter abbreviations.

151. See *Official USPS Abbreviations*, USPS, <https://www.usps.com/send/official-abbreviations.htm> (last visited Apr. 3, 2013).

- If the case is on appeal from the United States Court of Federal Claims, the abbreviation COFC is used.
- If the case is on appeal from the International Trade Commission, the three-letter abbreviation ITC is used.
- If the case is on appeal from the Board of Patent Appeals and Interferences, the abbreviation BPAI is used.

(f) **Lower court result.** Variable.

0 = patent not invalid under Section 112;
1 = patent invalid for lack of enablement;
2 = patent invalid for insufficient written description;
3 = patent invalid for both lack of enablement and insufficient written description.

(g) **Federal Circuit result.** Variable.

0 = patent not invalid under Section 112;
1 = patent invalid for lack of enablement;
2 = patent invalid for insufficient written description;
3 = patent invalid for both lack of enablement and insufficient written description;
4 = genuine issue of material fact precludes summary judgment as to invalidity;
5 = patent invalid on other grounds so enablement or written description issue is moot;
6 = remanded because lower court applied law incorrectly.

(h) **En banc?** Variable.

Size of panel:

0 = three-judge panel decision;
1 = five-judge panel decision;
2 = en banc decision.

(i) **Procedural History.** Variable.

Stage at which lower court decision was made.

0 = summary judgment;
1 = on merits or JMOL;
2 = decided by BPAI.

(j) Panel judges. Text field.

Names of the three panel judges, unless en banc or larger panel.

(k) Technical background of the panel judges. Variable.

For a three-judge panel, where T = technical background and N = non-technical background (for en banc decisions, a “-” is entered instead):

0 = NNN;

1 = NNT;

2 = NTT;

3 = TTT.

From this, a binary variable was calculated. NNN and NNT panels were classed as “non-technical” (0); NTT and TTT panels were classed as “technical” (1). The two decisions with five-judge panels¹⁵² were both classed as “technical” panels, because both panels contained four out of five judges with technical backgrounds.¹⁵³ The two en banc decisions in the present study¹⁵⁴ were excluded from this part of the analysis because they were not readily classifiable as either “technical” or “non-technical”—the cases were before five out of nine¹⁵⁵ and five out of eleven¹⁵⁶ judges with technical backgrounds, respectively.

(l) Authoring judge. Text field.

Name of the authoring judge.

(m) Technical background of the opinion author. Variable.

0 = non-technical background;

1 = technical background.

152. *Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1340 (Fed. Cir. 2011); *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1366 (Fed. Cir. 2009).

153. Judges William Bryson (N), Arthur Gajarsa (T), Richard Linn (T), Alan Lourie (T), and Pauline Newman (T) decided *Hynix*. See *Hynix*, 645 F.3d at 1340. Judges Arthur Gajarsa (T), Alan Lourie (T), Kimberly Moore (T), Pauline Newman (T), and Randall Rader (N) decided *Martek*. See *Martek*, 579 F.3d at 1366.

154. *Hyatt v. Kappos*, 625 F.3d 1320, 1322 (Fed. Cir. 2010) (en banc); *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1339 (Fed. Cir. 2010) (en banc).

155. *Hyatt* was before Randall Rader (N), Pauline Newman (T), Alan Lourie (T), William Bryson (N), Arthur Gajarsa (T), Richard Linn (T), Timothy Dyk (N), Sharon Prost (N), and Kimberly Moore (T). See *Hyatt*, 625 F.3d at 1322.

156. *Ariad Pharmaceuticals* was before Paul Michel (N), Pauline Newman (T), Haldane Mayer (N), Alan Lourie (T), Randall Rader (N), William Bryson (N), Arthur Gajarsa (T), Richard Linn (T), Timothy Dyk (N), Sharon Prost (N), and Kimberly Moore (T). See *Ariad*, 598 F.3d at 1339.

(n) **Concurring and dissenting judges.** Variable.

Name(s) of judge(s) that concurred or dissented.

(o) **Technical background of the dissenting judge.** Variable.

0 = non-technical background;

1 = technical background;

- = no dissent.

(p) **Subject matter.** Text field.

Broad subject matter of the patent in suit.

(q) **Written Description and Enablement Requirements.** Variable.

Are the written description and enablement requirements separate?

0 = no;

1 = yes;

- = not discussed.

(r) **Written Description Focus.** Variable.

Was Section 112 written description issue related to earliest available filing date?

0 = no;

1 = yes;

- = case does not involve written description issue.

(s) **Board of Patent Appeals and Interferences Issue.** Variable.

If case arose on appeal from the BPAI, was case (0) appealed by patentee because of a denied patent application or (1) appealed from an interference proceeding?

(t) **Notes.** Text field.

Any other relevant information.